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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,436	03/27/2001	Remi Delansorne	01056	5099

7590

12/16/2004

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EXAMINER

SNEDDEN, SHERIDAN

ART UNIT

PAPER NUMBER

1653

DATE MAILED: 12/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/787,436	Applicant(s) DELANSORNE ET AL.	
	Examiner Sheridan K Snedden	Art Unit 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 2/26/04.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-78 is/are pending in the application.
- 4a) Of the above claim(s) 29-31, 42-44 and 53-57 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-28, 32-41, 45-52 and 58-78 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/27/01</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's amendment filed 3/27/2001 is acknowledged. Applicant's cancellation of claims 1-20 and amendment of claims 23, 28, 31-34, 41, 44-45, 52, 55-56, 58, 60, and 62 is acknowledged. Applicant's addition of new claims 63-78 is acknowledged. Claims 21-78 are pending.
2. Applicant's election filed 2/26/2003 of invention I, claims 21-28, 32-41, 45-52 and 58-78 is acknowledged. Applicant's additional election of an LH-RH analogue of formula [D-Leu⁶-Npg⁷-Pro⁹-NH₂] LH-RH, which is pGlu-His-Trp-Ser-Tyr-D-Leu-Npg-Arg-Pro-NHC₅H₅. Claims 29-31, 42-44, 53-57 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 21-28, 32-34, and 63-65 are rejected under 35 U.S.C. 102(b) as being anticipated by Hirai *et al.* (US 4659696). Hirai *et al.* teaches an LH-RH analog which is a polypeptide having the formula pGlu-His-Trp-Ser-Tyr-D-Ala-Leu-Arg-Pro-NHC₂H₅ (or leuporelin) and 5 g

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of alpha-cyclodextrin. This analog fits the formula of claims A, I, II, III, AND IV defined in claims 23, 24, 25, 26, 27. Tri-O-methylcyclodextrin is also taught (column 4). "Absorption enhancer" in claim 34 is being interpreted as any excipient or pharmaceutical carrier that would increase the stability of the peptide. Thus, the excipient or pharmaceutical carriers used by Hirai *et al.* would meet this limitation.

Claim 22 recites limitations that refer to the intended use of the pharmaceutical formulation. Where it is possible that structural differences exist between the formulation of Hirai *et al.* and that of the present invention, there is nothing recited in the claims that distinguishes the present invention from the prior art.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 21-28, 32-41, 45-52, 58-65, and 66-78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hirai *et al.* (US 4,659,696) in view of Mehlem (US 2003/0162721 A1). Hirai *et al.* teaches an LH-RH analog which is a polypeptide having the formula pGlu-His-Trp-Ser-Tyr-D-Ala-Leu-Arg-Pro-NHC₂H₅ (or leuporelin) and 5 g of alpha-cyclodextrin. This analog fits the formula of claims A, I, II, III, AND IV defined in claims 23, 24, 25, 26, 27. Tri-O-methylcyclodextrin is also taught (column 4). "Absorption enhancer" in claim 34 is being interpreted as any excipient or pharmaceutical carrier that would increase the stability of the peptide. Thus, the excipient or pharmaceutical carriers used by Hirai *et al.* would meet this limitation. Claim 22 recites limitations that refer to the intended use of the pharmaceutical formulation. Where it is possible that structural differences exist between the formulation of Hirai *et al.* and that of the present invention, there is nothing recited in the claims that distinguishes the present invention from the prior art.

The present method claims are directed to a method of orally administering an LH-RH analog with alpha-cyclodextrin. Whereas Hirai *et al.*, teach the composition of the claims, non-oral administration routes are taught as the preferred method of administration. Thus, Hirai *et al.* does not expressly teach a method of oral administration, but only allows an inference that an method was employed with reduced success.

However, the teachings of Mehlem teach that peptides for oral administration are made up as capsules that may contain alpha-cyclodextrin. Mehlem employs alpha-cyclodextrin for the oral administration of peptides which is the problem that the present invention seeks to resolve.

Thus, it would have been obvious to the person of ordinary skill in the art at the time the invention was made to combine the LH-RH peptides of Hirai *et al.* with alpha-cyclodextrin for

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the purposes of oral administration. A person of ordinary skill in the art would have been motivated to use the formulation for administration as capsules comprising alpha-cyclodextrin have been used for the oral administration of peptides with some success. Thus, the claimed invention was within the ordinary skill in the art to make and use at the time it was made and was as a whole, *prima facie* obvious.

Conclusion

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan K Snedden whose telephone number is (571) 272-0959.

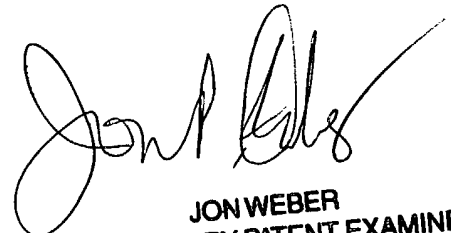
The examiner can normally be reached on Monday - Friday, 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571) 272-0925. The fax phone number for regular communications to the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SKS
December 13, 2004

SKS


JON WEBER
SUPERVISORY PATENT EXAMINER